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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,142	11/24/2003	Dan T. Simionescu	CXU-379	4675

22827 7590 09/21/2006

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EXAMINER	
KUMAR, PREETI	
ART UNIT	**PAPER NUMBER**
1751	

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/722,142	SIMIONESCU ET AL.	
	Examiner	Art Unit	
	Preeti Kumar	1751	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Final Rejection

1. Claims 20-29 are pending. Claim 20 is independent.

2. Claims 1-19 and 41-46 are cancelled. Claims 30-40 are withdrawn from consideration as being drawn to a non-elected invention.

Response to Amendment

3. The rejection of claims 20, 21, 23-24 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bachhuber et al. (US 4,588,579) is withdrawn in light of applicants amendment to the claims requiring the fixed tissue to be implantable.

4. The rejection of claims 22, 25-29 under 35 U.S.C. 103(a) as being unpatentable over Bachhuber et al. (US 4,588,579) is withdrawn in light of applicants amendment to the claims requiring the fixed tissue to be implantable.

5. The rejection of claims 22, 25-27 under 35 U.S.C. 112, second paragraph, is maintained. Claims 22, 25-27, recite limitation to process steps, ie (exposure to an elastase, glutaradehyde fixative and various properties thereafter) within a composition claim. It is indefinite if patent protection is sought for the process steps of exposure to an elastase, glutaradehyde fixative or if patent protection is sought for the composition of an implantable fixed tissue including a residue of phenolic tannin crosslinking agent.

6. The rejection of claims 20-21, 23-24, and 28 under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Adkisson (US 6,645,764) is maintained.

7. The rejection of claims 22, 25-27 under 35 U.S.C. 103(a) as being unpatentable over Adkisson (US 6,645,764) is maintained.

Response to Arguments

8. Applicant's arguments filed 6/30/2006 have been fully considered but they are not persuasive.

Applicants urge that Adkisson fails to disclose or suggest an implantable fixed tissue including a residues of a phenolic tannin crosslinking agent. Contrary to applicants arguments, Adkisson teach neocartilage matrix of skeletal muscle and other connective tissue is fixed with glutaraldehyde and tannic acid. See col.6,ln.2-3.

Applicants urge that Adkisson describes utilization of tannic acid as a stain preparation alon gwith osmium teroxide and uranyl acetate which are toxic materials and thus render the tissue cultures non implantable. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. Furthermore, Adkisson clearly indicated that the neocartilage composition are useful as implants and as replacement tissue for damaged or defective cartilage. See Abstract, third paragraph, first sentence.

Applicant's request for rejoinder of Group III, claims 20-29 and Group IV, claims 30-40 in the reply filed on 7/03/2006 is acknowledged. The traversal is on the ground(s) that these claims are related as combination/subcombination and require 2-way distinctness for maintenance of a restriction requirement. The inventions of groups III

and IV are 2 independent and distinct inventions; there is no support material in the claims of group III and thus he implantable fixed tissue of claims 20-29 is independent and distinct from the bioprosthetic comprising a support material attached to the implantable tissue of claims 30-40. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

New Grounds of Rejection

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 20-24 and 28-29 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nimmi et al. (US 5,374,539).

Nimni et al. teach that collagenous tissues selected from the group consisting of tendons, heart valves, pericardium, ligaments, skin, blood vessels, fascia, cartilage and intestine are used as sources of purified collagen and for manufacturing bioprosthesis contain significant amounts of other substances (elastin, glycoproteins, polysaccharides, cell derived materials, etc.). This process becomes therefore useful to selectively preserve the collagen in its native conformation and to eliminate

contaminants. The method described allows for enzymatic removal of all extraneous materials while preserving the native collagen molecules in their original fiber configuration. Subsequently this network of native collagen fibrils can be crosslinked using standard bifunctional crosslinking reagents, such as tannin. See abstract and claims 9 and 11.

Nimni et al. provides motivation to one of ordinary skill in the art to crosslink the fibrillar network with tanning reagents to preserve their structure, and decrease the ionic strength thus allowing the molecules to disperse into a suspensions of monomeric or polymeric collagen. The first of these approaches is used in the generation of collagen bioprosthesis which have now been cleared of the extraneous macromolecules which were entrapped in the interstices of the fibrillar network. It has been noted that such treated tissues become lighter in color and more pliable, an effect that is particularly evident after such matrices are crosslinked with bifunctional reagents such as glutaraldehyde (0.2% solution). See col.4,ln.20-30. This teaching of pliability property achieved with the tannin, encompasses the material limitation to the claimed implantable fixed tissue exhibiting at least 60% less calcification over being fixed with glutaradehyde.

Accordingly the teachings of Nimni et al. anticipate the material limitations of the instant claims.

Alternatively, even if the teachings of Nimni et al. are not sufficient to anticipate the material limitations of the instant claims, it would have been nonetheless obvious to one of ordinary skill in the art, to arrive at an implantable fixed tissue including a residue

of phenolic tannin crosslinking agent because Nimni et al. teach pericardial collagen crosslinked with natural tannin to produce a pliable, implantable bioprosthetic.

11. Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nimmi et al. (US 5,374,539).

Nimni et al. is relied upon as set forth above.

Nimni et al. are silent as to the claimed properties of the fixed tissue having a thermal denaturation temperature greater than 70 C, and less than 20% degradation after 48 hours.

However, it is reasonable to presume said properties to calcification, denaturation and degradation are encompassed by the fixed tissue of Nimni et al. because the presumption is supported by the use of similar materials (i.e. pericardial collagen) and in the similar production steps (i.e. contacted with natural tannin and gluteraldehyde) to produce an implantable bioprosthetic. The burden is upon the applicant to prove otherwise. *In re Fitzgerald*, 205 USPQ 594.

Claim Rejections

12. Claims 20-21, 23-24, and 28 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Adkisson (US 6,645,764).

Adkisson teach neocartilage matrix of skeletal muscle and other connective tissue is fixed with glutaraldehyde and tannic acid. See col.6,ln.1-10 and col.14,ln.11-12. Adkisson teach that the neocartilage may be mammalian neocartilage, including

human and porcine, or avian neocartilage. See col.10,ln.42-50. Accordingly the teachings of Adkisson anticipate the material limitations of the instant claims.

Adkisson is silent as to the fixed tissue comprising crosslinked elastin and crosslinked collagen. However, it is reasonable to presume that said limitations are encompassed by the invention of Adkisson because the presumption is supported by the use of similar materials (i.e. neocartilage, skeletal muscle and other connective tissue) and in the similar production steps (i.e. contacted with phenolic tannin cross linking agent and gluteraldehyde cross linking agent) to produce a fixed tissue. The burden is upon the applicant to prove otherwise. *In re Fitzgerald*, 205 USPQ 594.

13. Claims 22, 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adkisson (US 6,645,764).

Adkisson is relied upon as set forth above.

Adkisson are silent as to the claimed properties of the fixed tissue having 60 % less calcification, a thermal denaturation temperature greater than 70 C, less than 20% degradation after 48 hours.

However, it is reasonable to presume said properties to calcification, denaturation and degradation are encompassed by the fixed tissue of Adkisson because the presumption is supported by the use of similar materials (i.e. biological tissue) and in the similar production steps (i.e. contacted with phenolic tannin and gluteraldehyde) to produce the fixed tissue. The burden is upon the applicant to prove otherwise. *In re Fitzgerald*, 205 USPQ 594.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Preeti Kumar whose telephone number is 571-272-1320. The examiner can normally be reached on M-F 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas Mc Ginty can be reached on 571-272-1029. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Preeti Kumar PK.
Examiner
Art Unit 1751

PK

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SUPERVISORY PATENT EXAMINER
1751